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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/404,076	09/23/1999	ROBERT E. CANFIELD	48879-B/JPW/	8015

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EXAMINER

NOLAN, PATRICK J

ART UNIT	PAPER NUMBER
1644	15

DATE MAILED: 05/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>09/404,076</b>	Applicant(s) <b>Canfield et al.</b>
	Examiner <b>Patrick J. Nolan</b>	Art Unit <b>1644</b>
		
<i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i>		
<b>Period for Reply</b>		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.		
- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).		
<b>Status</b>		
1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>Oct 30, 2002</u>		
2a) <input checked="" type="checkbox"/> This action is <b>FINAL</b> .      2b) <input type="checkbox"/> This action is non-final.		
3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.		
<b>Disposition of Claims</b>		
4) <input checked="" type="checkbox"/> Claim(s) <u>4</u> is/are pending in the application.		
4a) Of the above, claim(s) <u></u> is/are withdrawn from consideration.		
5) <input type="checkbox"/> Claim(s) <u></u> is/are allowed.		
6) <input checked="" type="checkbox"/> Claim(s) <u>4</u> is/are rejected.		
7) <input type="checkbox"/> Claim(s) <u></u> is/are objected to.		
8) <input type="checkbox"/> Claims <u></u> are subject to restriction and/or election requirement.		
<b>Application Papers</b>		
9) <input type="checkbox"/> The specification is objected to by the Examiner.		
10) <input type="checkbox"/> The drawing(s) filed on <u></u> is/are a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
11) <input type="checkbox"/> The proposed drawing correction filed on <u></u> is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.		
12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.		
<b>Priority under 35 U.S.C. §§ 119 and 120</b>		
13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. <u></u> . 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).		
*See the attached detailed Office action for a list of the certified copies not received.		
14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) The translation of the foreign language provisional application has been received.		
15) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.		
<b>Attachment(s)</b>		
1) <input type="checkbox"/> Notice of References Cited (PTO-892)		
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)		
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). 		
4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). 		
5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)		
6) <input type="checkbox"/> Other: _____		

Part III DETAILED ACTION

1. This application is a continuation of 08/763,669 which claims benefit of provisional application 60/008,502.

2. Claim 4 is pending.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 4 stands rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has no support for an antibody that competitively inhibits the binding of the B505 antibody to hLH $\beta$  core fragment.

Applicant argues they have support for an antibody that competitively inhibits the B505 antibody to the hLH $\beta$  core fragment by the disclosure of competitive binding immunoassays between a series of monoclonal antibodies isolated because of their ability to bind the hLH $\beta$  core fragment with high affinity and specificity. However, the breadth of the claims encompass antibodies outside the scope of antibodies identified by the disclosed immunoassays. One example of such an antibody would be an anti-idiotypic antibody which was made specifically against the B505 antibody. This anti-idiotypic antibody would competitively inhibit the binding of the B505 antibody to the hLH $\beta$  core fragment by specifically binding to the B505 idiotypic region thereby sterically hindering the ability of the B505 antibody to bind the hLH $\beta$  core fragment. Furthermore, such an antibody would meet the limitations of an antibody which competitively inhibits because increasing concentrations of the anti-Id antibody would increasingly block the ability of the B505 antibody to bind the hLH $\beta$  core fragment. Since Applicant's disclosure does not specifically disclose a genus antibody that competitively inhibits the binding of the B505 antibody to hLH $\beta$  core fragment, and they are relying on what one of skill in the art performing the immunoassays disclosed in the specification would necessarily arrive at, and the breadth of the claim encompasses additional antibodies outside the disclosure of competitive immunoassays, the genus claimed antibodies do not have adequate written disclosure.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Thursday from 9:30 am to 4:30 pm.

7. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

*Pat J. Nolan*

Patrick J. Nolan, Ph.D.  
Primary Examiner, Group 1640  
April 24, 2003